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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,776	06/18/2007	Masato Miyake	690121.408USPC	2445

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,776	MIYAKE ET AL.	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,8,9,11-18 and 20-54* is/are pending in the application.

4a) Of the above claim(s) *3,5,9 and 24-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,8,11-18 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed July 13, 2009 in response to the Office Action of April 13, 2009, is acknowledged and has been entered. Claims 1, 3-5, 8, 9, 11-18, 20-54 are pending. Claims 1, 4, 8, and 18 are amended. Claims 2, 6, 7, 10, and 19 are canceled. Claims 3, 5, 9, and 24-54 remain withdrawn. Claims 1, 4, 8, 11-18, and 20-23 are currently being examined.

Rejection Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 4, 8, 11-18, and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection. NOTE: the rejection is maintained with regards to "cellular adhesion related agent" and addresses the amendments to antibodies that "interact with a cellular adhesion molecule." The rejection with regards to "gene introduction reagents" is withdrawn in view of amendments (see section 3 of the previous Office Action).

The claims are now drawn to a composition comprising: a) **a cellular adhesion related agent,** wherein the cellular adhesion related agent comprises an **interaction substance interacting with a cellular adhesion molecule and wherein the interaction substance is an antibody or a derivative thereof**; and b) a target substance comprising a genetic material; wherein the composition enhances the introduction efficiency of the target substance into a cell.

The specification discloses that "cellular adhesion related agent" refers to an agent suppressing the adhesion of a cell to another substance such as a support, other cells or the like. Such an agent includes, but is not limited to interaction substances which interact with a cellular adhesion molecule. The adhesion suppression activity of such interaction substances may be confirmed by the co-existence of an interaction substance when a cell is seeded onto a surface coated with an ECM substrate such as fibronectin. Furthermore, when substrates having such interaction activity are chemically or physically immobilized onto a surface, progress of adhesion property onto the surface of the cell is confirmed. "Interaction substances" include, but are not limited to, for example, substances allosterically interacting with a competitor, a partner in an antigen-antibody reaction (an antibody when the partner is an antigen, and an antigen when the partner is an antibody), a partner in a receptor-ligand relationship (a ligand when the partner is a receptor, and a receptor when the partner is a ligand), and the like. In the present invention, as long as cellular adhesion is enhanced, the object of the present invention (introduction of a target substance) may be achieved and thus it is to be understood that such agents are not particularly limited to a specific embodiment

([0063]). The "cellular adhesion related agent" used in the present invention comprises an interaction substance interacting with a cellular adhesion molecule such as an extracellular matrix molecule, integrin receptor, RGD molecules and the like ([0206]). In a preferable embodiment, the "interaction substance" used in the present invention causes an antigen-antibody reaction with a partner of a cellular adhesion molecule. Accordingly, the interaction substances of the present invention may be an antibody (for example, monoclonal antibodies, polyclonal antibodies, and the like), or derivatives thereof (chimeric antibodies, antibody fragments and the like) ([0207]). Preferably, the interaction substance comprises an antibody against an anti-integrin molecule, including CD49a-f relating to CD49 ([0208]). An antibody against an anti-integrin molecule, including CD29, may also be included in the preferable embodiments of the present invention ([0210]). The specification does not disclose any other cellular adhesion related agents, or antibodies or derivatives thereof interacting with a cellular adhesion molecule, or interacting with integrin receptors as broadly encompassed in the claims.

The art (see Scott et al, J of gene Medicine, 2001, 3:125-134) teaches integrin binding motif "RGD" and an integrin binding antibody, anti-CD29 antibody, that would function as an interaction substance that binds an integrin, and a cationic liposome that would act as a gene introduction reagent, however RGD, anti-CD29 antibody, and cationic liposome do not provide an adequate representative number of species to support adequate written description for the broad genus of cellular adhesion related agents, antibodies or derivatives thereof interacting with a cellular adhesion molecule, or interacting with integrin receptors as encompassed by the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of "cellular adhesion related agent," or "interaction substance interacting with a cellular adhesion molecule and wherein the interaction substance is an antibody or a derivative thereof". Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that " [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. At 1567, 43 USPQ2d at 1405. The court also stated that:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not

> specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such

characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. Thus, the instant specification may provide an adequate written description of cellular adhesion related agents, antibodies or derivatives thereof interacting with a cellular adhesion molecule, or interacting with integrin receptors, per Lilly by structurally describing representative cellular adhesion related agents, antibodies or derivatives thereof interacting with a cellular adhesion molecule, or interacting with integrin receptors or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe cellular adhesion related agents, antibodies or derivatives thereof interacting with a cellular adhesion molecule, or interacting with integrin receptors useful in the claimed invention in a manner that satisfies either the Lilly or Enzo standards. Although the specification discloses interaction substance comprises an antibody against an anti-integrin molecule, including CD49a-f relating to CD49 or an antibody that binds CD29, this does not provide a description of the broadly claimed cellular adhesion related agents, antibodies or

derivatives thereof interacting with a cellular adhesion molecule, or interacting with integrin receptors that would satisfy the standard set out in Enzo because the specification provides no structural features coupled to the claimed functional characteristics. Further, the function of "interacting" for the claimed antibody is unclear because the reaction or "interaction" with the cellular adhesion molecule or integrin receptor is unclear.

Further, the specification also fails to describe cellular adhesion related agents, antibodies or derivatives thereof interacting with a cellular adhesion molecule, or interacting with integrin receptors by the test set out in Lilly because the specification describes only interaction substances comprising an antibody against an anti-integrin molecule, including CD49a-f relating to CD49 or an antibody that binds CD29. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of cellular adhesion related agents, antibodies or derivatives thereof interacting with a cellular adhesion molecule, or interacting with integrin receptors, that is required to practice the claimed invention.

Examiner suggests amending the claims to recite that the interaction substance is an antibody or antibody fragment that binds to an integrin receptor.

Response to Relevant Arguments

3. Applicants argue that cell adhesion molecules are adequately described in the specification and well-known in the art and point to pages 13 and 14 of the specification and to Elangbam et al and state that the copy is attached (p. 11). Applicants argue that antibodies for cell adhesion molecules are exemplified in the specification and were well known in the art at the time of filing. Applicants argue that one having skill in the art could easily generate antibodies specific to a given cell adhesion molecule because sequences of such molecules were known at the time of filing (p. 12).

The arguments have been considered but are not found persuasive. The claims are still drawn to a broad genus of "cellular adhesion related agents" and "cellular adhesion molecules" with unknown structure for the reasons of record, as well as antibodies that are supposed to "interact" (an undefined function) with "cellular adhesion molecules", and the specification and claims do not define the structural features commonly possessed by members of the genus that can distinguish it from others. There is no recitation or disclosure of structural features common to the members of each "cellular adhesion related agent" and "cellular adhesion molecule" genus or which features constitute a substantial portion of the genus. The specification and claims do not identify which structural features are conserved among the "cellular adhesion related agents" and "cellular adhesion molecules", or which structures constitute a substantial portion of the genus in order for one to visualize or recognize the identity of the members of the genus, hence the written description for the genus of "cellular adhesion related agents" and "cellular adhesion molecules" in the claimed composition

do not meet the standards of Lilly. Although the specification discloses specific integrin receptors and antibodies that **bind** (a defined function) to them, neither the claims nor the specification teach the structures critical to the function, *i.e.*-"interacting with", of the broad genus of antibodies, or "cellular adhesion" of the broad genus of molecules and substances. There are no specific structures, identifying characteristics, partial or complete structures, or functional characteristic coupled with a known or disclosed structure for the broad genus of "cellular adhesion related agents" and "cellular adhesion molecules" as recited in the claims, hence the specification does not provide adequate written description according to the standards of Enzo. Applicants were not in possession of the broadly claimed genus at the time of filing.

To clarify further, the claimed antibodies and derivatives are not required to bind the cellular adhesion molecule, hence the antibodies cannot be defined by their antigen. The function of "interacting with" does not require antibody binding. Relevant to *Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin* (CAFC, 02-1187, 1/20/2004), the instant specification does not adequately describe the structure of "cellular adhesion molecules" for the reasons of record, hence the antibodies "interacting with," or even binding, this genus of molecule also lack adequate written description.

Finally, Applicants did not submit any copy of a Elangbam et al reference, hence Examiner cannot properly assess the reference and its relevance to the claims.

New Rejections

(necessitated by amendments)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 4, 8, 11-18, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al (Cancer gene Therapy, 2000, 7:683-696) in view of Fortunati et al (Gene Therapy, 2000, 7:1505-1515, IDS) and Sugano et al (Cancer Research, 2000, 60:6942-6949), as evidenced by GIBCO product insert for OPTI-MEM® (Form No. 2017, June 2001, one page) and Kamata et al (J of Biological Chemistry, 1994, 269, 26006-26010).

The claims are altered in scope and are now drawn to a composition comprising: a) a cellular adhesion related agent, wherein the cellular adhesion related agent comprises an interaction substance interacting with a cellular adhesion molecule and wherein the interaction substance is an antibody or a derivative thereof; and b) a target substance comprising a genetic material; wherein the composition enhances the introduction efficiency of the target substance into a cell (claim 1), wherein the cellular adhesion molecule is an integrin receptor (claim 4), a composition according to claim 1, wherein the interaction substance is a monoclonal or polyclonal antibody (claim 8), a composition according to claim 1, wherein the target substance comprises a nucleic

acid molecule (claim 11), a composition according to claim 1, wherein the target substance comprises DNA (claim 12), a composition according to claim 4, wherein the integrin receptor is CD29 (claim 13), a composition according to claim 4, wherein then integrin receptor is selected from the group consisting of CD29 (claim 14), a composition according to claim 4, wherein the integrin receptor interacts with a molecule selected from the group consisting of collagen, fibronectin, vitronectin and laminin (claim 15), a composition according to claim 1, wherein the cell comprises at least one cell selected from the group consisting of a stem cell and a differentiated cell (claim 16), a composition according to claim 1, wherein the cellular adhesion molecule is specifically expressed in the cell (claim 17), a composition according to claim 1, wherein the composition further comprises a gene introduction reagent selected from the group consisting of a cationic macromolecule, cationic lipid, and calcium phosphate (claim 18), a composition according to claim 1 further comprising a salt (claim 22), a composition according to claim 22, wherein the salt is selected from the group consisting of salts comprised in a buffer and salts comprised in media (claim 23).

Zou et al teach a composition comprising cationic liposome complexed to p53 cDNA for gene therapy of lung cancer (abstract; p. 684, col. 2). Zou et al teach successful treatment of lung tumors *in vivo* comprising administering the liposomes complexed to p53 cDNA (p. 692, col. 1-2; Figure 5). Zou et al demonstrate the composition enhances introduction efficiency of the p53 cDNA into cells (Tables 1-6; Figures 1-3 and 5). Zou et al teach the composition is comprised in Opti-Mem® media (p. 685, col. 1, first paragraph).

As evidenced by the GIBCO product insert for OPTI-MEM®, this media comprises salt sodium bicarbonate (see Formulation, col. 1). As evidence by Kamata et al, CD29 integrin inherently binds to collagen.

Zou et al do not teach that the composition comprises antibodies that bind integrin or CD29.

Fortunati et al teach and suggest complexing cationic polymers to β_1 integrin targeting ligands for targeted delivery of genes, and demonstrate that transfection efficiencies are increased for plasmid (genetic material) complexed with a cationic polymer targeted to β_1 integrin into cancer cells expressing β_1 integrin (abstract; p. 1506, col. 1; Figures 6). Transfection efficiencies were improved for DNA targeted to β_1 integrin over DNA not targeted (Figure 5). Fortunati et al suggest using the complexes for targeting tumors expressing integrins (p. 1512, col. 2, last paragraph).

Sugano et al teach a composition comprising a liposome conjugated to anti-β_1 integrin (CD29) monoclonal antibodies, wherein the liposome is loaded with the anti-cancer drug doxorubicin (abstract; "Materials and Methods"), wherein the liposomes were targeted to lung cancer *in vivo,* successfully treating tumors, and demonstrated to internalize efficiently (p. 6943, col. 2, "Results"). Sugano et al teach that doxorubicin-loaded liposomes conjugated to anti-β_1 integrin antibodies increased survival time of mice with lung tumors significantly whereas doxorubicin-loaded liposomes conjugated to a control antibody or to no antibody yielded survival times similar to mice that received no treatment (p. 6946, col. 1, first paragraph). Sugano et al teach that β_1 integrin has proven to be a viable target for establishing proof of principle for immunoliposome

delivery to a human lung tumor. The anti-β_1 integrin antibodies were successful and effective at targeting the selective binding of the liposomes to β_1 integrin in lung tumors and were internalized (p. 6948, col. 1, second paragraph). Sugano et al teach β_1 integrin is expressed in many different kinds of tumors (p. 6948, col. 1, paragraph 3).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to complex the anti-β_1 integrin (CD29) monoclonal antibodies taught by Sugano et al to the cationic liposome for gene delivery taught by Zou et al because the addition of antibodies for targeting of liposomes and drug delivery was known. One would have been motivated to add the anti-β_1 integrin antibodies of Sugano et al to the cationic liposome for gene delivery taught by Zou et al in order to target the gene delivery to lung cancer cells and because Fortunati et al specifically suggest targeting gene delivery to cells expressing β_1 integrin, such as tumors. One of ordinary skill in the art would have a reasonable expectation of success complexing the anti-β_1 integrin antibodies to the cationic liposome/DNA composition of Zou et al because methods of complexing the anti-β_1 integrin antibodies to liposomes are known, and Sugano et al demonstrate successful complexing of anti-β_1 integrin antibodies to liposomes. One of ordinary skill in the art would have a reasonable expectation of success enhancing the introduction efficiency of the gene or DNA of Zou et al by adding anti-β_1 integrin antibodies to the cationic liposomes because Fortunati et al demonstrate improved transfection of genes by targeting β_1 integrin, and Sugano et al demonstrate improved drug delivery and cancer treatment by targeting β_1 integrin with anti-β_1 integrin antibody-complexed liposomes.

5. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al (Cancer gene Therapy, 2000, 7:683-696) in view of Fortunati et al (Gene Therapy, 2000, 7:1505-1515) and Sugano et al (Cancer Research, 2000, 60:6942-6949), as evidenced by GIBCO product insert for OPTI-MEM® (Form No. 2017, June 2001, one page) and Kamata et al (J of Biological Chemistry, 1994, 269, 26006-26010) as applied to claims 1, 4, 8, 11-18, 22, and 23 above, and further in view of Martin et al (Gene Therapy and Molecular Biology, 1998, 1: 173-214).

The claims are drawn to a composition according to claim 1, further comprising a particle (claim 20), a composition according to claim 20, wherein the particle comprises a gold colloid (claim 21).

Zou et al, Fortunati et al, and Sugano et al (the combined references) teach a composition comprising a cationic liposome complexed to anti-β_1 integrin antibodies and DNA for enhanced delivery of the DNA to tumor cells, as set forth above.

The combined references do not teach that the composition further comprises a gold colloidal particle.

Martin et al teach labeling liposomes with colloidal gold for purposes of visualizing their localization *in vivo* or in cells by electron microscopy (p. 180, Figure 6, col. 1). Martin et al teach that colloidal gold is used to serve as a marker to follow liposome distribution by microscope techniques and used to view liposome distribution in tumors (p. 191, Figure 20; p. 192, col. 1, first paragraph; p. 202, col. 2, last paragraph). Martin et al teach liposomes are used for gene therapy of lung cancers (p.

203, Table 4, section 190; p. 205, section 208; section VIII) and can be tagged with antibodies to target specific tissues (abstract; section VII).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to and one would have been motivated to add colloidal gold to the composition taught by the combined references for purposes of visualizing liposome distribution in tumors, particularly for lung tumors. One of ordinary skill in the art would have a reasonable expectation of success adding colloidal gold to the composition of the combined references because labeling of liposomes with colloidal gold is known.

6. All other rejections recited in the Office Action mailed April 13, 2009 are hereby withdrawn in view of amendments and arguments. The composition taught by Scott et al (see section 4 of the previous Office Action) fails to enhance the introduction efficiency of the target substance/genetic material into a cell because the anti-β_1 integrin antibodies incubated with the cell impeded the ability of the RGD motif peptide to deliver the DNA to the cell, hence the rejection under 35 U.S.C. 102(b) is withdrawn.

7. **Conclusion:** No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION.

IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. ' 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Primary Examiner, Art Unit 1642